PATENT
Docket No.: 12013/48803

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Inventor:	Richard S. KUSLEIKA	Group Art Unit:	3763
Application No.:	10/825,309	Confirmation No.:	7747
Filing Date:	April 16, 2004	Examiner:	Quynh-Nhu Hoang Vu
For:	CATHETER FOR TISSUE DILATATION AND DRUG DELIVERY		

Mail Stop Appeal Brief - Patents
COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, VA 22313-1450

REPLY BRIEF

S I R :

In response to the Examiner's Answer dated January 22, 2010, the Appellant respectfully submits this Reply Brief pursuant to 37 C.F.R. § 41.41.

New Evidence Cited By the Examiner and Rebuttal Evidence

In the Examiner's Answer, the Examiner cites two references that were not previously of record in this application, specifically, Rey (U.S. Patent No. 5,413,822) and Woodyard (U.S. Patent No. 3,651,591). (Examiner's Answer, pp. 7-8.) In rebuttal of that newly-cited evidence, Appellant cites herein the following additional references:

U.S. Patent No. 5,800,540 to Chin;

U.S. Patent No. 5,474,563 to Myler et al.;

Material Properties, www.plasticsintl.com (attached as Exhibit A); and

Polyvinyl Chloride (PVC): It's Hard to Imagine Life Without It, www.americanchemsitry.com (attached as Exhibit B).

Because this evidence is in direct rebuttal to evidence first cited by the Examiner in the Examiner's Answer, the Appellant respectfully requests consideration of this evidence, in the context of the arguments set forth below.[1]

Group I (Claims 16, 19-21 and 24)

In Appellant's Appeal Brief, Appellant argued that Shockey (U.S. Patent No. 4,994,033) differs from Appellant's claim 16 for at least two important reasons. First, Shockey does not disclose an outer treatment sheath "formed of an elastic material." Second, Shockey does not disclose the step of "while maintaining the dilatation balloon in an unexpanded condition, supplying a treatment fluid under pressure to a compartment formed by the treatment sheath, to elastically expand the treatment sheath radially into a substantially conforming contact with the surrounding tissue at the treatment site [and] cause the treatment fluid to pass through the treatment sheath from the compartment to the surrounding tissue."

In response, the Examiner's Answer contends that Shockey's disclosure of polyethylene tetrathalate (PET) and polyvinyl chloride (PVC) constitutes disclosure of "elastic" materials. The Examiner asserts, "It is very well-known in the art that polyethylene tetrathalate or polyvinyl chloride is soft or elastic." (Examiner's Answer, p. 5.) The Examiner points to Sogard and two

[1] Concurrently with this Reply Brief, Appellant is filing a petition under 37 CFR 1.181(a) requesting that, on account of the new evidence cited by the Examiner, the ground of rejection set forth in the Examiner's Answer be designated as a new ground of rejection. MPEP § 1207.03.

newly-cited references as allegedly showing that elasticity is "inherent" in these materials disclosed in Shockey. (Examiner's Answer, pp. 5-8.)

The Examiner also contends that Shockey meets the limitation of expanding the treatment sheath into "substantially conforming contact" with the tissue while maintaining the inner balloon unexpanded. The Examiner's Answer states that "substantially conforming contact" is a term that the Examiner "interprets very broadly [to mean] that the outer treatment sheath 22 is almost or nearly [in] contact with the surrounding tissue." (Examiner's Answer, p. 11.) Thus, according to the Examiner, "substantially conforming contact" does not require any contact. Based on this construction, the Examiner finds that the Shockey outer member is in "substantially conforming contact" with the tissue since it is "nearly" in contact with the tissue.

In reply to these assertions in the Examiner's Answer, the Appellant provides the following remarks.

The sentence in Shockey relied upon by the Examiner for the disclosure of an outer treatment sheath "formed of an elastic material" is as follows:

> Where the expander member 22 comprises a biaxially oriented thermosetting plastic material such as **polyethylene tetrathalate or polyvinyl chloride**, the micropores 28 may be formed using a precision laser.

(Shockey, col. 3, lines 12-16 (emphasis added).) The Examiner asserts that this disclosure in Shockey meets the requirement in claim 16 of an outer treatment sheath "formed of an elastic material," because, as the Examiner contends, it is "very well-known in the art that polyethylene tetrathalate or polyvinyl chloride is soft or elastic." (Examiner's Answer, p. 5.) That contention, however, is factually incorrect.

Polyethylene tetrathalate (PET) and polyvinyl chloride (PVC) are both generally ***inelastic*** materials, characterized by relatively ***high*** moduli of elasticity. For example, U.S. Patent No.

5,800,540 to Chin states, "The balloon may be made of polyethylene, polyethylene terephthalate (PET), polyvinyl chloride [PVC], or other generally ***inelastic*** materials." (Chin, col. 5, line 67 - col. 6, line 3 (emphasis added).) Similarly, U.S. Patent No. 5,474,563 to Myler et al. states that a conventional balloon material may be used, for example, "… a relatively ***inelastic*** material such as PET … ." (Myler, col. 5, line 9 (emphasis added).)

The modulus of elasticity of both PET and PVC evidences that they are both substantially inelastic. According to Plastics International, the modulus of elasticity of both PET and PVC is on the order of 400,000 psi. (*See Material Properties*, www.plasticsintl.com (attached as Exhibit A), listing the tensile modulus of PET as 400,000 psi and of PVC as 411,000 psi.)

Based on the Appellant's specification, a person of ordinary skill in the art would understand what materials could be used to achieve an "elastic" treatment sheath and a "substantially inelastic" dilatation balloon, and such a person would have considered both PET and PVC to be "substantially inelastic." For the treatment sheath, the Appellant's specification states that the sheath may be formed, for example, of "an elastic biocompatible polymer, *e.g.* latex." The specification states that the elastic material may have "a modulus of elasticity in the range of about 2,000 to 80,000 psi." (Specification, paras. 15, 47.) For the dilatation balloon, the specification lists possible materials, including, for example, "nylon" and other materials that can be selected as "substantially inelastic" materials. (Specification, paras. 14, 45.)

In connection with a Request for Reconsideration filed May 19, 2008, the Appellant previously submitted a table from The Engineering Toolbox (www.EngineeringToolBox.com), showing the modulus of elasticity of various materials. For comparison, the modulus of elasticity of rubber and nylon are shown below:

Material	Modulus of Elasticity (psi)
Rubber	1,450 – 14,500[2]
Nylon	290,000 – 580,000[3]

A person of ordinary skill in the art would plainly understand, from Appellant's disclosure, that a material such as rubber or latex with a relatively low modulus of elasticity is "elastic" within the meaning of Appellant's disclosure, and a material such as nylon or another material with a relatively high modulus of elasticity as compared to the elastic material of the treatment sheath is "substantially inelastic" within the meaning of Appellant's disclosure. The materials PET and PVC, both of which have high moduli of elasticity similar to nylon, would be understood to be "substantially inelastic." Moreover, Appellant's specification specifically lists both PVC and PET as materials that can be used for a "substantially inelastic" dilatation balloon. (Specification, paras. 14, 45.)

The Examiner's Answer cites Sogard and two newly-cited references as allegedly showing that PVC is inherently elastic; however, that conclusion is based on a misunderstanding about PVC. Because of its nature, PVC ***can be*** made to be more compliant by the addition of plasticizers. (*See, e.g., Polyvinyl Chloride (PVC): It's Hard to Imagine Life Without It*, www.americanchemsitry.com (Exhibit B) ("PVC may be manufactured to be either rigid or flexible. … Flexible PVC, used to make raincoats and shower curtains, for example, is manufactured using compounds known as plasticizers, which make the material soft and

---

[2] The modulus of elasticity of rubber is listed as 0.01 $x10^9$ N/m^2 – $0.1x10^9$ N/m^2, which is approximately 1,450 psi – 14,500 psi (using a conversion of 1 N/m^2 = $1.45x10^{-4}$ psi).

[3] The modulus of elasticity of nylon is listed as 2 $x10^9$ N/m^2 - $4x10^9$ N/m^2, which is approximately 290,000 psi – 580,000 psi (using a conversion of 1 N/m^2 = $1.45x10^{-4}$ psi).

flexible.").) Thus, when Sogard states that polyvinyl chloride (PVC) can be used to make a high-compliant balloon (col. 2, lines 28-35), it does not mean that PVC is always compliant or inherently compliant; it means only that, when desired, a high-compliant version of PVC may be used to manufacture a high-compliant balloon. The other references cited by the Examiner as allegedly demonstrating that PVC is inherently elastic, namely Rey (U.S. Patent No. 5,413,822) and Woodyard (U.S. Patent No. 3,651,591), are similar in that they demonstrate, at most, that PVC ***can be*** flexible, not that it is always or inherently flexible.

In the context of the Shockey disclosure, a person of ordinary skill in the art would have understood that the PVC in that disclosure is meant to be substantially ***inelastic***. For example, in Shockey, PVC and PET are disclosed as alternative materials, and PET was well-known to be used as a common material for substantially inelastic non-compliant balloons. (*See*, *e.g.*, Sogard, col. 2, lines 50-52; Specification, para. 45.)

At minimum, however, the PVC in Shockey is not inherently elastic, as the Examiner's Answer asserts. "[A] prior art reference may anticipate without disclosing a feature of the claimed invention if that characteristic is *necessarily* present, or inherent, in the single anticipating reference." *Toro Co. v. Deere Co.*, 355 F.3d 1313, 1320 (Fed. Cir. 2004) (citation omitted) (emphasis added). Moreover, "[i]nherency … may not be established by probabilities or possibilities. The mere fact that a certain thing *may* result from a given set of circumstances is not sufficient." *In re Oelrich*, 666 F.2d 578, 581 (C.C.P.A. 1981) (emphasis added). Here, the PVC in Shockey is certainly not *necessarily* elastic. Accordingly, Shockey cannot be relied upon for inherent disclosure of an outer treatment sheath "formed of an elastic material."

The Examiner relies only on the argument that the outer member in Shockey is inherently elastic and has not alleged that it would have been obvious to modify Shockey to include an

elastic outer member. As discussed in Appellant's Appeal Brief, the Examiner cites no evidence as to why a person of ordinary skill in the art would choose an "elastic" material for the outer sleeve of Shockey. Because the proposed combination fails to meet the limitation of an outer treatment sheath "formed of an elastic material," the rejection should be reversed.

As to the Examiner's "very broad" interpretation of "substantially conforming contact" to mean "that the outer treatment sheath 22 is almost or nearly [in] contact with the surrounding tissue" (Examiner's Answer, p. 11), this interpretation is unreasonably overbroad. A proper interpretation of the term "substantially conforming contact" requires that there is contact, and that the contact "substantially" conforms to the contours of the vessel. The word "substantially" modifies the word "conforming." The requirement of "substantially conforming contact" cannot be met where there is no contact at all, as the Examiner asserts.

As pointed out in the Appellant's Appeal Brief, Shockey explicitly states that its drug delivery from the outer sleeve and vessel dilatation from the inner sleeve should be "simultaneous" and "at the same time." (Shockey, col. 2, lines 5 & 41; col. 4, lines 8-9.) Thus, Shockey does not show an outer member expanded to "substantially conforming contact" with the surrounding tissue while the inner balloon remains unexpanded. Because Shockey's "simultaneous" process cannot be modified to Appellant's claimed two-step process without destroying the explicit teachings of Shockey, and because such a modification is nowhere suggested by the prior art, the rejection of claim 16, and all claims depending therefrom, should be reversed.

Group II (Claims 17, 18, 22 and 23)

Dependent claim 17 recites that, following the dilatation of the tissue, the dilatation balloon is contracted while the treatment sheath is maintained in contact with the tissue to

administer the treatment fluid to the tissue. As argued in Appellant's Appeal Brief, nothing in Shockey or Sogard suggests maintaining Shockey's outer expander in contact with tissue and delivering treatment fluid after the inner member is contracted. In fact, as stated above, since Shockey explicitly states that its drug delivery and tissue dilatation are "simultaneous" and "at the same time," it would be contrary to the Shockey reference for drug delivery to occur after contraction of the inner dilatation member.

In response, the Examiner's Answer cites the Machold reference (U.S. Patent No. 5,611,775) as allegedly showing that Shockey includes an "enabled disclosure" for this feature. However, claim 17 recites method steps, and Shockey simply does not perform the claimed method. Specifically, claim 17 recites the step of "following said dilatation, radially contracting the dilatation balloon while maintaining the treatment sheath in said contact to administer the treatment fluid to the dilatated tissue." Shockey not only does not perform this step, it states that its drug delivery and tissue dilatation are "simultaneous" and "at the same time." Machold in no way evidences that Shockey contains an "enabled disclosure" for the method of claim 17.

Thus, for the foregoing reasons, the rejection of claim 17 and all claims depending therefrom should be reversed.

Group III (Claims 38 and 39)

Dependent claim 38 recites that the treatment sheath is formed of a biocompatible elastomeric material consisting essentially of at least one of the following: latex, urethane, silicone, and a thermoplastic elastomer. To support the rejection of claim 38, the Examiner's Answer relies on the argument that the PET and PVC in Shockey are inherently elastic materials. This argument is flawed, for the reasons given above. Accordingly, the rejection of claim 38, and claim 39, which depends therefrom, should be reversed.

CONCLUSION

For the foregoing reasons, the Appellant respectfully requests favorable consideration of this appeal by the Board and reversal of the final rejection of claims 16-24, 38 and 39.

The Office is hereby authorized to charge any additional fees under 37 C.F.R. §1.16 or §1.17 or credit any overpayment to Deposit Account No. 11-0600.

Respectfully submitted,

Date: 22 March 2010

/Douglas E. Ringel/
Douglas E. Ringel
Registration No. 34,416

KENYON & KENYON LLP
1500 K Street, N.W.
Washington, D.C. 20005-1257
Tel.: (202) 220-4200
Fax: (202) 220-4201

Customer Number 23838